510(K) SUMMARY"
AS REQUIRED BY SECTION 807.92(c)
Modified May 27, 2014

510(k) Owner's Name, Address, Telephone Number, Fax Number, Contact Person and Date Prepared.

Surgical Theater
781 Beta Drive
Mayfield Village, Ohio 44143
Phone: (216) 496-7884
Fax: (216) 916-3806

Contact Person:

Mordechai Avisar
CEO/President
Surgical Theater, LLC
781 Beta Drive
Mayfield Village, Ohio 44143
Phone: (216) 496-7884
Fax: (216) 916-3806
Email: mavisar@surgicaltheater.net

Date Prepared: March 22, 2014

Name of Device

- Trade Name: Surgical Navigation Advanced Platform (SNAP)
- Common Name: Image Management Software
- Classification Name: Medical Image Management System Product Code LLC

Predicate Device

The Surgical Navigation Advanced Platform (SNAP) substantially equivalent to the Surgical Theater, LLC Surgery Rehearsal Platform (K123023).

Device Description:

The SNAP is software based medical image management system. It is intended for use as a software interface and image segmentation system for the transfer of imaging information from a CT or MR medical scanner to an output file. It is also intended for use

in simulating and evaluating surgical treatment options both pre-operatively and intra-operatively with validated systems as identified in the device labeling.

The SNAP system is based on the Surgical Theater Surgery Rehearsal Platform (SRP) image management system. The SRP was cleared by FDA on February 12, 2013 under 510(k) Accession Number K123023.

The SNAP utilizes the same identical software as the SRP to create 3D models of patient data from 2D scan slices. This provides the user with ability to input, display, color, and manipulate the 2D scan slices via a 3D representation.

The cleared SRP device interfaces with an input from external 3D mouse device (Omni), which allows the surgeons to navigate the simulated instruments within the said 3D image.

The SNAP system enhances the SRP's capability by adding additional input and allowing the surgeon to connect to an external Image Guided System and Navigation systems (in general; "IGS"; for example Brainlab Kolibri or Brainlab Curve), and to see the incoming navigation data in the SNAP monitor. The incoming navigation data is then displayed to the surgeon inside the generated 3D model, so the surgeon gets a 3D representation of his surgery navigation session.

Current navigation systems usually display the navigation data on 2D black and white DICOM imagery within the external navigation system itself. The SNAP displays the same navigation data (Pointer position and orientation), as it is received from the external navigation system, in a 3D fashion inside the SNAP 3D model of the anatomy as it is reconstructed from the original DICOM slices.

Device Function

The SNAP device takes 2D medical images (DICOM dataset) and reconstructs a 3D model of a specific patient's anatomy. Using the existing data segmentation and visualization capabilities of the SRP, the SNAP system allows the surgeon to connect to external navigation systems and display navigation data (i.e. pointer from IGS) inside its own 3D model. This provides surgeons with additional navigation feedback during surgery.

The two main differences between the SRP and the SNAP are the input device being the navigation systems in the SNAP Vs the Omni device in the SRP and the use in the Operating Room of the SNAP Vs the Pre-Operating Room use of the SRP.

Except for these two differences, the SRP and the SNAP are identical. They are made from the same code (software) and are manufactured by the same company (Surgical

Theater). They share the same features and performance characteristics utilize the same identical technology and both function in the same identical manner.
The underlying method of connectivity to the external device is the same in the SRP and SNAP; both devices present the external device's movements based on information obtained directly from the external device and it relays on the accuracy of the external device.

Scientific Concepts

The SNAP is based on the concept of transforming stacked medical images (DICOM dataset) to a 3 dimensional model of patient specific anatomy, and applying visualization algorithms and filters on that 3D model, to control its visualization representation to get a better understanding of the case at hand.

Furthermore, the SNAP connectivity to an external IGS (i.e. Navigation System) expands the visual model by displaying the navigation data inside the 3D model.

Significant Physical and Performance Characteristics

Design:

The Surgical Navigation Advanced Platform (SNAP) is a software based device running on "of the shelf" commercial components. The design is based on an advanced, touch screen friendly, Graphical User Interface (GUI) that runs an underlying simulation engine to process the medical data and user inputs, and an image generator software engine that is used to display a high end 3D model of the medical data (DICOM).

The underlying simulation engine includes a navigation connectivity module that allows external IGS systems (i.e. navigation systems) to send navigation data into the SNAP system, to be displayed within its internal 3D model.

Materials:

The Surgical Navigation Advanced Platform is a software based and commercial off the shelf personal computer system (i.e. PC, keyboard, mouse, touchscreen monitor etc.). Materials used in these systems have been used in offices, homes, hospitals and other applications for many years in both medical and non-medical applications, with no adverse effects.

Physical Properties:

The physical properties of the Surgical Navigation Advanced Platform are the same as any software based, and commercial off the shelf personal computer system (i.e. PC, keyboard, mouse, touchscreen monitor etc.).

Indications for Use:

The Surgical Theater, LLC SNAP is intended for use as a software interface and image segmentation system for the transfer of imaging information from a CT or MR medical scanner to an output file. It is also intended for use in simulating and evaluating surgical treatment options both pre-operatively and intra- operatively with validated systems as identified in the device labeling.

Predicate Device Comparison

The Surgical Theater SNAP is substantially equivalent to the Surgical Theater Surgery Rehearsal Platform (SRP) (K123023).

SNAP/SRP Comparative Analysis

Characteristic	Surgical Navigation Advanced Platform (SNAP)	Surgery Rehearsal Platform	Explanation of Differences
510(k) Accession Number	TBD	K123023	NA
Clearance Date	TBD	2/12/2013	NA
Computer	PC Workstation	PC Workstation	NA
Image Sources	CT and MRI	CT and MRI	NA
Indications for Use	Software interface and image segmentation system for the transfer of imaging information from CT or MR medical scanner to an output file. It is also intended for use in simulating and evaluating surgical treatment options both preoperatively and intraoperatively with interface to external navigation systems with OpenIGTLink Capability.	Software interface and image segmentation system for the transfer of imaging information from CT or MR medical scanner to an output file. Pre-operative software for simulating/evaluation surgical treatment options.	Unlike the SRP, The SNAP is also intended to be used in the OR during surgery.
Data Transfer Method	CD or USB	CD or USB	NA
Preoperative Planning	Yes	Yes	NA
Patient Contact	No	No	NA
Human Intervention for Interpretation of	Yes	Yes	NA

Characteristic	Surgical Navigation Advanced Platform (SNAP)	Surgery Rehearsal Platform	Explanation of Differences
Images			
Capability of creating 3D models of patient data from 2D scan slices.	Yes	Yes	NA
Provides the user with ability to input, display, color, and manipulate the 2D scan slices via a 3D representation.	Yes	Yes	NA
Image tools such as rotation, scaling and coloring.	Yes	Yes	NA
Capability of connecting to an external Surgical Navigation system (for example Brainlab Kolibri or Brainlab Curve), and processing the incoming navigation data.	Yes	No	Unlike the SRP that connected to a 3D mouse (Omni), the SNAP is designed to connect via a network connection, to an external navigation system, and display the incoming navigation data on its own 3D model of the DICOM data. The underlying method of connectivity to the external device is the same in the SRP and SNAP; both devices present the external device's movements based on information obtained directly from the external device and it relays on the accuracy of the external device.
Intra-operative Use	Yes	No	Unlike the SRP, The SNAP is also intended to be used in the OR during surgery.
Pre-operative Use	Yes	Yes	NA

Performance Data: (Non-clinical Testing)

The Surgical Theater SNAP Software was fully tested, verified and validated by Surgical Theater as part of its' own internal design control requirements. Furthermore, the SNAP was validated by two neurosurgeons based on historical DICOM cases (of patients' cases who had their surgeries done in the past). Verification and validation results confirm that the SNAP Software meets its' performance requirements. The SNAP was tested with the Brainlab Kolibri 2 and Brainlab Curve systems which had "Brainlab Cranial Version 2.1" with an active license for the "IGT Link" connectivity module.

The SNAP System was tested to and meets the requirements of IEC 60601-1-2 Standard for Electromagnetic Interference and Susceptibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 27, 2014

SURGICAL THEATER, LLC
MORDECHAI AVISAR
781 BETA DR.
MAYFIELD VILLAGE OH 44143

Re: K140819
Trade/Device Name: Surgical Navigation Advanced Platform
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 28, 2014
Received: May 29, 2014

Dear Mr. Avisar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041

or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140819

Device Name
Surgical Theater, LLC
Surgical Navigation Advanced Platform

Indications for Use *(Describe)*
The Surgical Theater, LLC SNAP is intended for use as a software interface and image segmentation system for the transfer of imaging information from a CT or MR medical scanner to an output file. It is also intended for use in simulating and evaluating surgical treatment options both pre-operatively and intra- operatively with validated systems as identified in the device labeling.

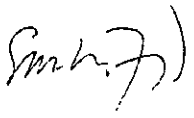
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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